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DEC 1 2 2011

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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC™ 3DSi Locking Screws.

A.1. Submitted By: Wright Medical Technology, Inc.
5677 Airline Rd
Arlington, TN 38002

Date: October 28, 2011

Contact Person: Peggy S. Rivers

Regulatory Affairs Specialist

(901) 867-4759

A.2. Proprietary Name: **ORTHOLOC™ 3DSi Locking Screws**

Common Name: Locking Screws

Device Classification Regulation: 21 CFR 888.3030—Class II

Device Product Code & Panel: HRS: Plate, Fixation Bone

87 Orthopedics

A.3. Predicate Device: K102352—EVOLVE® EPS ORTHOLOC™ System

A.4. Device Description

The ORTHOLOC™ 3DSi Locking Screws are made from implant grade stainless steel and are available with cortical and cancellous thread forms in multiple length and diameters.

These screws are manufactured from stainless steel conforming to ASTM F2229.

The design features of the ORTHOLOC™ 3DSi Locking Screws are identical to the design features of the predicate devices EVOLVE® EPS ORTHOLOC™ System Locking Screws.

WRIGHT.

A.5. Intended Use

The system indications for both subject ORTHOLOC™ 3DSi Locking Screws and predicate EVOLVE® EPS ORTHOLOC™ (**K102352**) are identical.

EVOLVE® EPS ORTHOLOC™ System is intended for fixation of fractures, osteotomies and nonunions of the olecranon, humerus, radius, and ulna.

A.6. Technological Characteristics Comparison

The subject ORTHOLOC™ 3DSi Locking screws are identical to the previously cleared EVOLVE® EPS ORTHOLOC™ Locking screws (**K102352**) with only minor change to feature call-outs on the engineering drawing.

B.1. Substantial Equivalence – Non-Clinical Evidence

Substantial equivalence is demonstrated through materials information and a composition of design characteristics.

B.2. Substantial Equivalence – Clinical Evidence

N/A

B.3. Substantial Equivalence - Conclusions

The subject screws are identical in indication for use, diameter, size range and material to the predicate. No new types of safety and effectiveness questions can be expected. From the evidence given in the Premarket Notification, the subject devices can be expected to perform at least as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 1 2 2011

Wright Medical Technology, Inc.
% Ms. Peggy S. Rivers
5677 Airline Rd.
Arlington, TN 38002

Re: K113339
Trade/Device Name: Ortholoc™ 3DSi Locking Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: November 11th, 2011
Received: November 14th, 2011

Dear Ms. Rivers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113339

Device Name: EVOLVE® EPS ORTHOLOC ™ System with ORTHOLOC™ 3DSi Locking Screws

Indications For Use:

EVOLVE® EPS ORTHOLOC™ System: Intended for fixation of fractures, osteotomies and nonunions of the olecranon, humerus, radius, and ulna

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113339